REMARKS

I. Introduction

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

In the specification, paragraphs have been amended on pages 5 and 7.

Claims 8-14 and 20 are requested to be cancelled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

Claims 6-7, 15, 18 and 21 are currently being amended. The phrase "comprising administering to a subject in need of such therapy" is supported by the description of section "Administration routes and pharmaceutical formulations" on page 34, line 32 to page 35, line 7. In addition, "ADCC activity" is supported by the description on page 33, lines 10 to 12.

Claim 22 is new.

Applicants thank the Examiner for searching both breast and ovarian cancer. Office Action, p. 3. As the Examiner has searched both of these cancers, the entire subject matter of claim 22 should be examined.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 1-7, 15-19 and 21-22 will remain pending in the application.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Response to Issues Raised by Examiner in Outstanding Office Action

a. Restriction Requirement

The Office reasserts its restriction requirement and based on Hirano has denied Applicants' arguments. The present invention is directed to a method for the treatment of solid cancers. Examples 1 and 2 show that an anti-HM1.24 antibody has ADCC activity common to different solid cancers. This is a "special technical feature" shared by all of the inventions in this application. All of the claims should, therefore, be examined together in one application. Hirano does not mention the treatment of cancers, tumors, or any disease covered by the claims. Accordingly, the current claims should be examined together. Applicants request reconsideration by the Office.

b. Priority

The Office has objected to the priority claim because Applicants have not submitted a certified English translation of the PCT application or the Japanese priority document. Applicants note that this application is a national stage filing provided under 35 U.S.C. § 371. As required under § 371(c)(2), Applicants have filed a translation of the PCT application when entering the national phase in order to be entitled to the priority date of the international application. Applicants also submit with this response a translation of JP 2003-352819. Applicants request that the PTO acknowledge the appropriate priority date.

c. Oath/Declaration

The Office has objected to the oath/declaration. Applicants submit with this response a new oath/declaration addressing the Office's concerns and believe the objection is now moot.

d. Abstract

The Office has objected to the Abstract. Applicants attach an amended abstract to address the Office's concerns and request withdrawal of the objection.

e. Specification

Applicants have amended the Specification as requested by the Office and respectfully request withdrawal of the objection.

f. Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 15-21 are rejected by the Examiner under 35 U.S.C. § 112, second paragraph as allegedly indefinite. Applicants have amended claims 15 and 18 to clarify the type of activity described and correct the improper antecedent bases objected to by the Examiner. See points a)-c) on page 5 of the Office Action. In addition, Applicants have amended the claims to include the administration of the antibody. See pages 5-6 of the Office Action. Applicants request reconsideration and withdrawal of the rejection.

g. Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 15-21 are rejected by the Examiner under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for a method for treating a solid tumor by administering an antibody that specifically binds to a protein having the amino acid sequence as set forth in SEQ ID NO. 2 *in vitro*, does not reasonably provide enablement for a method of treating a solid tumor by administering an antibody that contains only one complementarity determining region (CDR), or a method of treating a solid tumor *in vivo*. See Office Action, pp. 6-11.

As an initial matter, Applicants have amended the claims to clarify that the antibody used in the current method does not contain less than the full complement of six CDR regions. See Office Action pp. 7-9. For example, in claim 18, the antibody is a humanized antibody comprising the 6 CDRs. It is well known to one of skill in the art that the L-chain and H-chain each have 3 CDRs, and the total number of CDRs for an antibody is 6.

Applicants believe "[a]ny analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention." MPEP, 8th ed. Rev.2, 2164.01. See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) (The test of enablement is whether one reasonably skilled in the art

could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied* , 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.* , 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Applicants also note that *in vitro* data may be used to show correlation with *in vivo* effects and as evidence of enablement. As provided in the MPEP 2164.02:

> (1) CORRELATION: *IN VITRO/IN VIVO*
>
> The issue of "correlation" is related to the issue of the presence or absence of working examples. "Correlation" as used herein refers to the relationship between *in vitro* or *in vivo* animal model assays and a disclosed or a claimed method of use. An *in vitro* or *in vivo* animal model example in the specification, in effect, constitutes a "working example" if that example "correlates" with a disclosed or claimed method invention. If there is no correlation, then the examples do not constitute "working examples." In this regard, the issue of "correlation" is also dependent on the state of the prior art. In other words, if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate ...

There is sufficient evidence to show that the claimed method is enabled based on the specification and the knowledge of one of skill in the art. The Specification explicitly teaches the presence of a well established model for the *in vivo* activity of the anti-HM1.24 antigen based on the prior *in vitro* studies. The Background section of the application cites WO 98/35698, which corresponds to Koishihara (US 6503510). Example 4 (Figures 26 and 27) of Koishihara shows that an *in vivo* model using mice transplanted with lymphocyte cells

(CCRF-HSB-2 cells) exhibits an anti-tumor effect by administering anti-HM1.24 antigen. In addition, Example 1 (Figure 17) of Koishihara shows that HM1.24 antigen is expressed on CCRF-HSB-2 cells. These examples provide evidence in an *in vivo* system for the utility of anti-HM1.24 antibody in lymphocyte cancers which express the HM1.24 antigen.

The present application extends these findings and shows that HM1.24 antigen is expressed on solid cancers. See Example 1. Example 2 (Figure 4) shows that a humanized anti-HM1.24 antibody has ADCC activity on solid cancer. As the above cited art indicates the ability to deliver anti-HM1.24 antibody for the treatment of lymphocyte cancer in an *in vivo* system and the correlation of *in vitro* data to *in vivo* results, one of skill in the art would reasonably expect the current Application's *in vitro* data to correlate with *in vivo* results, as found in Koishihara.

Applicants respectfully requests reconsideration and withdrawal of the rejection.

h. Claim Rejections - 35 U.S.C. § 102

Claims 15-21 are rejected by the Examiner under 35 U.S.C. § 102 as being anticipated by Morin (US PG PUB 2003/0211498, PCT filed April 4, 2001). As noted above, Applicants have amended the method claims to include the administration of the provided antibody. The Office has apparently conceded that this therapeutic method step is not provided in Morin. See Office Action, page 13, lines 3-5. As Morin does not recite every element of the current claims it may not serve as a proper anticipatory reference. In addition, Applicants note that Morin does not describe or suggest the use of an anti-HM1.24 antibody having ADCC activity. Based on the above, Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant(s) hereby petition(s) for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Dec. 19, 2007

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